RD2009-04

Registration Decision

Gliocladium catenulatum strain J1446

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Overview

Registration Decision for *Gliocladium catenulatum* strain J1446

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, is granting full registration for the sale and use of *Gliocladium catenulatum* J1446 Dried Cell Mass and Prestop Biofungicide WP containing the technical grade active ingredient *Gliocladium catenulatum* strain J1446 for the suppression of a variety of fungal diseases on the following greenhouse-grown vegetables, herbs and ornamentals: cucumber, tomato, pepper, lettuce, cauliflower, broccoli, oregano, basil, parsley, thyme, dill, alyssum, geranium, pansy, petunia, salvia, snapdragon, tagetes, poinsettia and saintpaulia.

Current scientific data from the applicant were evaluated to determine whether, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision—*Gliocladium catenulatum* strain J1446 (PRD2008-03). This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Gliocladium catenulatum* strain J1446, and summarizes the Agency's decision and the reasons for it. Comments received were only for error correction and did not affect the risk assessment. This decision is consistent with the proposed registration decision stated in PRD2008-03.

For more details on the information presented in this Registration Decision, please refer to PRD2008-03, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of or exposure to the product under its conditions of registration.[3] The Act also requires that products have value[4] when used according

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety, environmental benefits and social, economic impact".

to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children), as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, as well as on the assessment process and risk-reduction programs, please visit the PMRA's website at www.healthcanada.gc.ca/pmra.

What Is *Gliocladium catenulatum* strain J1446?

Gliocladium catenulatum is a fungus that grows on dead organic matter that can be found commonly in soil worldwide. *G. catenulatum* strain J1446 was originally isolated as a microbial pest control agent (MPCA) due to its ability to suppress soil-borne fungal diseases on plants.

Health Considerations

Can Approved Uses of *Gliocladium catenulatum* strain J1446 Affect Human Health?

***Gliocladium catenulatum* strain J1446 is unlikely to affect your health when Prestop Biofungicide WP is used according to label directions.**

Exposure to *G. catenulatum* strain J1446 may occur during handling and application of Prestop Biofungicide WP. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g. production of toxic byproducts); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies and the levels to which people may be exposed, relative to exposures already encountered in nature to other isolates of the microorganism.

Toxicology studies in laboratory animals describe potential health effects from large doses in an effort to identify any potential to cause disease or toxicity. When *G. catenulatum* strain J1446 was tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk. Strains of *G. catenulatum* are common in nature and the use of Prestop Biofungicide WP in greenhouses to suppress fungal plant disease on vegetables, herbs and ornamentals is not expected to significantly increase the natural environmental background levels of this microorganism. Furthermore, when *G. catenulatum* strain J1446 was administered orally to rats, no signs that it caused toxicity or disease were observed. Although secondary metabolites of toxicological significance have been shown to be produced by other isolates of *G. catenulatum*, due to the demonstrated low toxicity and absence of such metabolites in cultures of *G. catenulatum* strain J1446, the risks from secondary metabolites for the general population, including infants and children, are negligible. The establishment of a maximum residue limit (MRL) is therefore not required for *G. catenulatum* strain J1446. As well, the likelihood of residues of *G. catenulatum* strain J1446 contaminating drinking water supplies is negligible to nonexistent. Consequently, dietary exposure and risk are minimal to nonexistent.

Occupational Risks From Handling Prestop Biofungicide WP

Occupational risks are not of concern when Prestop Biofungicide WP is used according to label directions, which include protective measures.

Growers handling Prestop Biofungicide WP can come into direct contact with *G. catenulatum* strain J1446 on the skin, in the eyes or by inhalation. For this reason, the label specifies that growers exposed to Prestop Biofungicide WP during handling, mixing/loading, application or clean-up/repair activities must wear waterproof gloves, a long-sleeved shirt, long pants, eye goggles, shoes, socks and a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any –95, R-95, P-95 or HE filter. Furthermore, early-entry workers will be restricted from entering areas where Prestop Biofungicide WP has been applied as a foliar spray for a period of four hours unless wearing the indicated personal protective equipment with the exception of eye goggles and a dust/mist filtering respirator, which are required only until the spray mist has settled.

Bystander exposure is expected to be much less than that of applicators, handlers and mixers/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Prestop Biofungicide WP is Introduced Into the Environment?

Environmental risks are not of concern.

Studies designed to examine the effects of *Gliocladium catenulatum* strain J1446 on various non-target organisms were evaluated. Few adverse effects were observed in birds, freshwater fish, terrestrial arthropods (including honeybees), aquatic invertebrates, marine animals or algae.

G. catenulatum is not generally considered to be a disease-causing agent. Therefore, Prestop Biofungicide WP is expected to present a negligible risk to non-target organisms.

Value Considerations

What Is the Value of Prestop Biofungicide WP?

Prestop Biofungicide WP suppresses specific soil and seed-borne pathogens and foliar diseases on greenhouse-grown vegetables, herbs and ornamentals.

The formulated end-use product, Prestop Biofungicide WP, is a biological fungicide. When applied in a 0.5–1.0% solution as a soil media treatment, a soil drench treatment or a foliar treatment, it will suppress specific soil and seed-borne pathogens and foliar diseases on greenhouse-grown vegetables, herbs and ornamentals. It is best used as a preventative before disease is present, and reapplication is necessary every three to six weeks depending on the disease pressures in the greenhouse and the method of application.

Prestop Biofungicide WP is considered to be a low-risk product and can be used as an integral part of an integrated pest management program to reduce the reliance on chemical alternatives. There are limited fungicide products currently available to greenhouse growers; therefore, Prestop Biofungicide WP is a new product available to the greenhouse sector. It may also be used as a resistance management tool for rotation of fungicides where no other alternative products are available.

Measures to Minimize Risk

The labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Prestop Biofungicide WP to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**

  Because of concerns with users developing allergic reactions through repeated high exposures to *G. catenulatum* strain J1446, anyone handling, mixing/loading, applying or involved in clean-up/repair activities of Prestop Biofungicide WP must wear waterproof gloves, a long-sleeved shirt, long pants, eye goggles and a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any –95, R-95, P-95 or HE filter. Furthermore, early-entry workers will be restricted from entering areas where Prestop Biofungicide WP has been applied as a foliar spray for a period of four hours unless wearing the indicated personal protective equipment with the exception of eye goggles and a dust/mist filtering respirator, which are required only until the spray mist has settled.

- **Environment**

  As a general precaution, handlers are asked not to contaminate irrigation or drinking water or aquatic habitats through equipment cleaning or waste disposal. In addition, growers must not allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other water bodies.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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[5] As per subsection 35(1) of the *Pest Control Products Act*.

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